IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER #68

(Plaintiff's' Motion to Compel OUS Documents and
Ethicon's Motion for Protective Order)

This multidistrict litigation involves surgical mesh products designed, manufactured, marketed, and sold by Defendant, Ethicon, Inc., ("Ethicon") to treat pelvic organ prolapse and stress urinary incontinence. Two motions are pending regarding Ethicon's duty to produce documents located outside of the United States ("OUS" documents). (ECF No. 585, 699). Plaintiffs, all residents of the United States, seek an order compelling the production of documents prepared and maintained by Ethicon in the course of its overseas distribution of pelvic and abdominal mesh products. (ECF No. 585). Ethicon has produced some of the requested materials, but asks the court for a protective order limiting the extent of future productions or, in the alternative, requiring Plaintiffs to bear the costs of the discovery. (ECF No. 699). For the reasons that follow, the court **GRANTS** Plaintiffs' Motion to Compel, (ECF No. 585), and **DENIES** Ethicon's Motion for Protective Order. (ECF No. 699).

Positions of the Parties

According to Plaintiffs, they have had extensive discussions with Ethicon to resolve this discovery dispute and, as a result, have narrowed the subject matter of their requests to four areas of concern: testing, manufacturing, design, and foreign regulatory issues.[1] Plaintiffs argue that documents pertaining to these issues are highly relevant to their claims of design defect and failure to warn regardless of whether the information involves products distributed in the United States or overseas. They emphasize that certain products at issue in this litigation were originally designed and studied in countries other than the United States, and these studies form the basis of representations made by Ethicon in its global marketing of pelvic mesh products. Plaintiffs also argue that the knowledge Ethicon gained through distributing mesh products in foreign markets is particularly relevant to when Ethicon appreciated the nature and extent of complications associated with pelvic mesh. Plaintiffs contend that the federal rules do not limit relevant discovery to documents located within the United States, nor do the rules relieve Ethicon of its discovery obligations simply because production of OUS documents may be inconvenient.

Alternatively, Ethicon argues that it has already produced a substantial number of OUS documents, including millions of pages related to health, safety, and product marketing. Ethicon has supplied custodial files for 52 OUS custodians, marketing materials for 32 countries, and regulatory documents for three countries selected by Plaintiffs, including France, Australia, and Japan. In Ethicon's view, it should not be compelled to produce any additional regulatory documents for the simple reason that

[1] Ethicon concedes its obligation to produce OUS documents on the issues of testing, manufacturing, and design and, thereby, limits its motion for a protective order to the production of additional OUS regulatory documents.

the burden of gathering and producing such materials far outweighs any benefits to be derived by their production. Ethicon represents that it has regulatory submissions in 67 countries across the globe, and the materials are scattered among various custodians in each country. To fulfill Plaintiffs' requests, Ethicon will have to interview and collect documents from approximately 150 OUS employees, then translate and produce an estimated 150,000-250,000 pages at a cost of between $500,000 and $1,000,000. According to Ethicon, the regulatory documents have only a "tenuous connection" to the issues in dispute, given that courts generally do not admit evidence of foreign regulatory actions in cases governed by domestic law. Moreover, Ethicon argues that regulatory documents do not vary significantly from one country to another. Consequently, Plaintiffs are unlikely to discover more or different information from that which is already in their possession. The undersigned finds neither of these arguments to be persuasive.

Relevance of the Documents

Fed.R.Civ.P. 26(b) allows discovery "regarding any nonprivileged matter that is relevant to any party's claim or defense." It is well-established that "relevance" in the context of discovery is broader than relevance in the context of admissibility. *King v. Conde,* 121 F.R.D. 180, 194 (E.D.N.Y. 1988); *see, also, Caton v. Green Tree Services, LLC,* 2007 WL 2220281 (N.D.W.Va. 2007) (the "test for relevancy under the discovery rules is necessarily broader than the test for relevancy under Rule 402 of the Federal Rules of Evidence."); *Carr v. Double T Diner,* 272 F.R.D.431, 433 (D.Md. 2010) ("The scope of relevancy under discovery rules is broad, such that relevancy encompasses any matter that bears or may bear on any issue that is or may be in the case"). Indeed, the Rule explicitly states that "[r]elevant information need not be admissible at trial if the

discovery appears reasonably calculated to lead to the discovery of admissible evidence. Thus, Ethicon's argument that discovery of foreign regulatory documents is proscribed by their inadmissibility at trial is flawed, and the cases cited by Ethicon are not especially germane to the issue before the court. Clearly, documents submitted by Ethicon to foreign regulatory bodies concerning pelvic mesh products identical or similar to mesh products distributed in the United States are relevant to the claims and defenses in this litigation. Moreover, these materials are likely to contain information bearing on the issues of "what [Ethicon] knew about the potential risks of the products at issue here, when [Ethicon] knew about those potential risks, what follow-up investigations [Ethicon] did to learn more about those potential risks, and other facts that are potentially relevant" to Plaintiffs' claims of failure to warn and product defects. *Hardy v. Pharmacia Corp.,* Case No. 4:09-cv-119 (CDL), 2011 WL 2118983, at *3 (M.D.Ga. May 27, 2011). Accordingly, Plaintiffs are entitled to collect all OUS regulatory documents.

Burdensomeness/Duplication

Having determined the relevancy of the OUS regulatory documents does not end the analysis, however. Under Fed.Rule.Civ.P. 26(c), a party may move the court for an order precluding or limiting proposed discovery if necessary to protect the party from annoyance, embarrassment, oppression, undue burden or expense. The person or party moving for the protective order bears the burden of demonstrating good cause, *Minter v. Wells Fargo Bank, N.A.*, 258 F.R.D. 118, 124 (D.Md.2009), and in doing so, "may not rely upon 'stereotyped and conclusory statements,' but must present a 'particular and specific demonstration of fact,' as to why a protective order should issue." *Baron Fin. Corp. v. Natanzon,* 240 F.R.D. 200, 202 (D.Md.2006) (*quoting* 8A Charles Alan Wright

et al., *Fed. Prac. & Proc. Civ.* § 2035 (2d ed.1994)). The court has broad discretion under Fed.R.Civ.P. 26(c) "to decide when a protective order is appropriate and what degree of protection is required." *Seattle Times v. Rhinehart*, 467 U.S. 20, 36, 104 S.Ct. 2199, 81 L.Ed.2d 17 (1984). In crafting a protective order, the court "may be as inventive as the necessities of a particular case require in order to achieve the benign purposes of the rule." 8A Charles Alan Wright, Arthur R. Miller, & Richard L. Marcus, *Federal Practice and Procedure*, § 2036 (3d ed.).

Furthermore, under Fed.R.Civ.P 26(b)(2)(C), the court ***must***, on motion or on its own:

> limit the frequency or extent of discovery, otherwise allowed by these rules or by local rule if it determines that "(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

This rule "cautions that all permissible discovery must be measured against the yardstick of proportionality." *Lynn v. Monarch Recovery Management, Inc.*, 285 F.R.D. 350, 355 (D. Md. 2012) (quoting *Victor Stanley, Inc. v. Creative Pipe, Inc.*, 269 F.R.D. 497, 523 (D. Md. 2010)). "The application of [Rule 26(b)(2)(C)] involves a highly discretionary determination based upon an assessment of a number of competing considerations." *Sommerfield v. City of Chicago*, 613 F.Supp.2d 1004, 1017 (N.D.Ill.2009).

Ethicon contends that the regulatory documents from the remaining 64 countries are largely duplicative of the materials already produced to Plaintiffs. However, Ethicon

apparently has not reviewed these documents and makes this representation based almost entirely upon an investigation conducted by its expert in electronic discovery, Ms. Pamela Downs. In support of Ethicon's motion, Ms. Downs supplies an affidavit detailing her investigation, which is somewhat confusing. She indicates that country–specific regulatory submissions are stored in the country of registration and not aggregated in a central repository. Notwithstanding this representation, she adds that records for the United States and the European Union are aggregated in a database and in network shares. She suggests that foreign countries "rely upon" previously produced documents for their submissions, but then identifies six countries that have unique regulatory requirements such as independent or government-approved in-country laboratory or clinical testing. She states that labels and instructions for use pertinent to the various countries "originate" from a previously produced US Global Label content management system, but concedes that the labels actually used may be slight modifications of the Global Label. Taken as a whole, the affidavit contains internal inconsistencies that are difficult to resolve. More importantly, Ms. Downs's investigation simply does not establish to the court's satisfaction that the unproduced regulatory materials are "largely" duplicative.

In contrast to Ms. Downs's affidavit, Plaintiffs contend that they have already found significant variations among the documents produced from Japan, Australia, and France. Moreover, approximately fifteen different mesh products were marketed by Ethicon, and these products were distributed at different times in different countries and over a period of years. Given these facts, and the additional fact that regulatory submissions have been produced for less than five percent of the countries comprising Ethicon's pelvic mesh market, Plaintiffs have presented valid reasons to doubt the

representation that regulatory materials are substantially the same in every country. Accordingly, after hearing from both parties, the undersigned concludes that while Ethicon has a good faith belief that the remaining OUS regulatory documents are duplicative of what has already been produced, Ethicon has not carried its burden to justify a protective order. Until submissions from a larger percentage of the OUS market have be examined, the extent of duplication is speculative, and Ethicon's motion for protective order is premature.

Therefore, the court **GRANTS** Plaintiffs' motion to compel. Nonetheless, the parties are **ORDERED** to agree on a process to produce OUS regulatory materials in a manner that is most likely to resolve the question of whether future productions will be unreasonably duplicative. If the parties cannot agree within **seven (7) days**, then plaintiffs shall start by choosing ten additional countries for immediate production and list the remaining countries in order of priority. In this way, the parties should be able to identify in short order the core regulatory documents, if any, that are substantially the same in every country and can forgo future duplicate productions. This order is not intended to modify the ESI protocol, however. Therefore, to the extent that documents located and reviewed by Ethicon are identical to those already produced, Ethicon is not required to produce them again. (ECF No. 235-1 at 4).

Cost-Shifting

Ethicon asks the court to shift to Plaintiffs the costs of additional discovery of OUS regulatory materials on the basis that the anticipated yield of noncumulative, nonduplicative information is low while the estimated expense involved in collecting, translating, reviewing, and producing the documents is high; thus, constituting an unfair burden on Ethicon. As a general rule, "the presumption is that the responding

party must bear the expense of complying with discovery requests." *Oppenheimer Fund, Inc. v. Sanders,* 437 U.S. 340, 358, 98 S.Ct. 2380, 57 L.Ed.2d 253 (1978). However, the practice of shifting discovery costs, in whole or in part, from the responding party to the requesting party has been recognized for decades, *see Boeynaems v. LA Fitness Intern, LLC,* 285 F.R.D. 331, 338 (E.D.Pa. 2012); most frequently in the context of electronically stored information ("ESI"). *See McPeek v. Ashcroft,* 202 F.R.D. 31, (D.D.C. 2001); *Rowe Entertainment v. The William Morris Agency, Inc.* 205 F.R.D. 421 (S.D.N.Y.2002); *Zubulake v. UBS Warburg LLC ("Zubulake I"),* 217 F.R.D. 309 (S.D.N.Y. 2003). The responding party "has the burden of proof on a motion for cost-shifting." *Zubulake v. UBS Warburg LLC ("Zubulake II"),* 216 F.R.D. 280, 283 (S.D.N.Y.2003).

In *McPeek v. Ashcroft,* the district court acknowledged the potentially enormous expense involved in searching, collecting, and producing relevant ESI. Consequently, to balance the requesting party's entitlement to broad discovery with the responding party's right to be protected from undue burden and expense, the court borrowed from the economic principle of "marginal utility" and adopted an analytic methodology to determine if cost-shifting was appropriate. *McPeek,* 202 F.R.D. at 34. Using this methodology, the court examined the likelihood that ESI would contain information relevant to a claim or defense. The more likely it was that ESI was relevant, the fairer it was to have the responding party incur the expense of searching, collecting and producing the ESI. The less likely it was that a search of ESI would bear fruit, the more unjust it was to make the responding party shoulder that burden alone. Other courts have developed their own tests for assessing the merits of cost-shifting. For example, the

district court in *Rowe* developed an eight-factor balancing test,[2] *Rowe,* 205 F.R.D. at 429, while the court in *Zubulake I,* favored a seven-factor test.[3] In *Thompson v. U.S. Dept. of Housing and Urban Development*, 219 F.R.D. 93 (D.Md. 2003), the District Court of Maryland suggested that the balancing factors contained in Rule 26(b)(2) might be "all that is needed to allow a court to reach a fair result when considering the scope of discovery of electronic records."[4] *Id.* at 98. The *Thompson* court noted that "[r]egardless of which test is used, the most important ingredient for the analytical process to produce a fair result is a particularization of the facts to support any challenge to discovery of electronic records." Here, the records at issue are a combination of ESI and hard-copy documents. Irrespective of the format of the documents, the undersigned agrees with the *Thompson* court that a fair cost-shifting analysis can be achieved by applying the factors found in Rule 26(b)(2)(C). After considering those factors, the undersigned finds that cost-shifting is not appropriate at this time.

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[2] The eight factors include: (1) the specificity of the discovery requests; (2) the likelihood of discovering critical information; (3) the availability of such information from other sources; (4) the purposes for which the responding party maintains the requested data; (5) the relative benefit to the parties of obtaining the information; (6) the total cost associated with production; (7) the relative ability of each party to control cost and its incentive to do so; and (8) the resources available to each party.

[3] The seven factors are: (1) The extent to which the request is specifically tailored to discover relevant information; (2)The availability of such information from other sources; (3) The total cost of production, compared to the amount in controversy; (4) The total cost of production, compared to the resources available to each party; (5) The relative ability of each party to control costs and its incentive to do so; (6)The importance of the issues at stake in the litigation; and (7)The relative benefits to the parties of obtaining the information.

[4] As previously stated, the factors in Rule 26(b)(2) include: [W]hether the discovery sought is unreasonably cumulative or duplicative; whether the information sought is obtainable from some other more convenient, less burdensome or inexpensive source; whether the party seeking the information already has had adequate opportunity to obtain the information; and whether the burden or expense of the proposed discovery outweighs its likely benefit, taking into consideration the following: the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake in the litigation and of the discovery sought to the resolution of the issues.

Looking at the first factor, Ethicon has not convinced the court that the remaining regulatory documents are ***unreasonably*** cumulative or duplicative of the documents produced to date. While there will no doubt be some duplication, the extent of the overlap is uncertain; therefore, this factor is neutral. The next two factors weigh in favor of the presumption that the responding party should bear the costs of discovery. There is nothing before the court to suggest a less burdensome, less expensive, and more convenient source from which Plaintiffs can obtain the regulatory documents. To the contrary, Plaintiffs would likely have to approach each individual regulatory body to gather the documents. Likewise, Plaintiffs have not had an adequate opportunity to obtain the information. They have only received complete regulatory submissions from three out of 67 countries.

When considering the needs of the case, the amount in controversy, the resources of the parties, the importance of the issues at stake and of the discovery sought, the undersigned finds that these factors weigh against cost-shifting. This multidistrict litigation includes over ten thousand plaintiffs, claiming to be permanently injured by Ethicon's mesh products. In cases involving Ethicon's pelvic mesh that have gone to trial, the Plaintiffs' verdicts have been in the millions of dollars. Accordingly, the amount in controversy far exceeds the projected costs of producing the regulatory documents, even when considering the costs already incurred by Ethicon in the course of discovery. Moreover, Ethicon is part of a multibillion dollar family of companies; therefore, absorbing these discovery costs should not financially cripple Ethicon. In addition, the issues at stake are not only important to the thousands of plaintiffs that have been treated with Ethicon's mesh, but may have broad public impact in the way that similar products are designed, manufactured, tested, marketed, sold, and

implanted. *See Zubulake I*, 217 F.R.D. at 321. The final factor, the importance of the discovery, carries no particular weight at this juncture because the documents have not been reviewed in their entirety by either party. Certainly, a substantial potential exists that the documents will play an important role in the litigation. Consequently, until Plaintiffs begin to collect regulatory materials that, with some repetition, are substantially the same as those already in their possession, the factors set forth in Rule 26(b)(2)(C) do not favor cost-shifting. It plainly is too early in the collection process to determine with any certainty the likelihood that future productions of regulatory documents will be cumulative and duplicative.

Therefore, the court **DENIES** Ethicon's request for cost-shifting of the expenses incurred to produce OUS regulatory materials. Having found thus, however, the court grants Ethicon leave to re-file a motion for cost-shifting if further production supports its position that the unproduced regulatory documents are substantially similar to the documents previously supplied, such that, the expense of continuing to collect, translate, review, and produce them truly outweighs the likelihood that new information will be obtained.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327, and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-23147. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the

responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at **http://www.wvsd.uscourts.gov**.

ENTERED: September 18, 2013.

Cheryl A. Eifert
United States Magistrate Judge